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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,373	12/22/2003	Walter L. Carpenter	P-11209.04	9323
27581	7590	05/08/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/743,373

Applicant(s)

CARPENTER ET AL.

Examiner

Leslie R. Deak

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 10, 18, 19, 21, 22, 26-28 and 40-43 is/are rejected.
- 7) ☒ Claim(s) 2-9, 11-17, 20, 23-25, 29-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 29 is objected to because of the following informalities: The claim is dependent from claim 18, but recites limitations found in claim 28. Examiner has assumed that claim 29 should depend from claim 28. Appropriate correction is required.
2. Claim 42 is objected to because of the following informalities: It is not clear if applicant is claiming a plurality of different types of ports on a single connector. Appropriate correction is required.

Drawings

3. The drawings are objected to because the lines are unclear and several reference numbers are illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

Art Unit: 3761

the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18,19, 21, 22, 27, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,540,653 to Schock.

In the specification and figures, Schock discloses the device substantially as claimed by applicant. In particular, Schock discloses a cardiopulmonary bypass circuit 14/20 with a blood pump 10 that draws blood through the circuit, a venous air removal device and arterial filter (trap/filter 16) with a purge port 36, inlet 34 at the top of the device, and an outlet 44 at the bottom of the device, and oxygenator 12 (see FIG 1). The circuit comprises a support module 43/45 that cooperates with support arm 50 to hold the circuit, including tubing lines and treatment devices in place. The arm 50 is attached to vertical pole or mast 48, suspending the circuit (see FIG 1).

Schock does not disclose that the filter/trap and blood pump are directly connected. However, the pump disclosed by Schock acts to move blood through the circuit, just as the pump claimed by applicant. It has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP § 2144.04. Absent any showing of criticality of the location of the pump with regard to the air trap and/or filter, examiner considers the location of the parts to be a mere rearrangement of the parts of the device, since the device disclosed by Schock functions in the same manner claimed by applicant.

With regard to claims 19 and 27, Schock illustrates that filter/trap 16 (that is connected to support module 43/45) is configured to allow arm 50 to suspend the circuit from pole 48. It follows naturally that the trap/filter comprises a contact point or receptacle that allows the illustrated attachment, thus meeting the limitations of the claim.

With regard to claim 21, Schock discloses that the purge port 36 comprises a valve that opens to bleed air from the system. As such, examiner is interpreting the valve structure 36 to meet the limitations of applicant's claimed "air sensor" that allows for removal of air through the port.

With regard to claim 22, the trap/filter 16 has a blood inlet at the top of the device, creating an inlet chamber at the top of the filter 16. Blood outlet is at the bottom of the filter 16, and bleed valve 36 is at the top of the filter. It follows naturally that air in filter/trap 16 accumulates in the upper portion of the chamber.

With regard to claim 42, the tubing system is connected by means of barbed connectors (42, 52), meeting the limitations of the claim, which is unclear (see objection above).

6. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,540,653 to Schock, as applied above, in view of US 6,306,346 to Lindsay.

In the specification and figures, Schock discloses the device substantially as claimed by applicant with the exception of the circuit support comprising multiple fittings for blood treatment components and a support arm to hold electronics. Lindsay discloses an extracorporeal blood assembly with various tubing lines and blood treatment components that are held in place by carrier or support 82 that supports the blood handling apparatus, including a reservoir and oxygenator (see column 5, lines 39-61). The support 82 comprises pegs, attachment plates, mounting plates, and various other fittings that serve to maintain the blood handling components in discrete locations, allowing one item to be removed without disturbing the other components (see, generally, column 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add various support pegs and fittings as disclosed by Lindsay to the support structure disclosed by Schock in order to independently support and retain the tubing and blood treatment components for easy interchangeability, as taught by Lindsay.

With regard to claim 28, Schock discloses that the pole or mast 48 comprises at least two support arms 50, but does not disclose an adjustable clamp. Lindsay discloses an extracorporeal support assembly with a pole or mast 90 with support arms fastened

to the pole with adjustable clamps 96 that allow the user to select a height for clamping (see at least FIG 8, column 7, lines 1-10). Applicant's recitation of an arm to support an electronics assembly is considered to be a statement of the intended use of the device.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the support arms disclosed by Schock and Lindsay are capable of supporting an electronics assembly, meeting that limitation of the claim. Therefore, it would have been obvious to supply the support arms disclosed by Shock with an clamp assembly as disclosed by Lindsay in order to provide an adjustable mounting arm, as taught by Lindsay.

7. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,540,653 to Schock, as applied above, in view of US 6,824,524 to Favre.

In the specification and figures, Schock discloses the device substantially as claimed by applicant with the exception of a flow rate transducer. Favre discloses an extracorporeal support system comprising several tubing lines and measuring means for measuring the amount of fluid that passes through the system (see column 4, lines 28-33). The measuring devices may comprise flow rate detectors. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a flow rate transducer and its respective housing as disclosed by Favre to the tubing circuit disclosed by Schock in order to measure the amount of fluid flowing through the circuit, as taught by Favre.

Art Unit: 3761

8. Claims 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,540,653 to Schock, as applied above, in view of US 6,607,698 to Spears.

In the specification and figures, Schock discloses the device substantially as claimed by applicant with the exception of sensor devices and infusion/sampling ports. Spears discloses an extracorporeal support system with various tubing lines (see FIG 2) connected to monitors 22, 23 that may measure blood oxygen saturation of blood passing through the line in order to control the oxygenation procedure. The Spear device further comprises access ports 44, 46, to permit drug infusion or sampling (see column 8, lines 6-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to connect monitors and ports as disclosed by Spears to the fluid circuit disclosed by Schock in order to control the bypass procedure and infuse drugs or sample blood, as taught by Spear.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28 and 29 of copending Application No. 10/743,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because applicant is claiming an extracorporeal circuit as claimed in the copending application with the absence of the priming fluid circuit presented in the copending application. Once the applicant has received a patent for a species or a more specific embodiment (such as claimed in copending application 10/743,357), he is not entitled to a patent for the generic or broader invention without maintaining common ownership and ensuring that the term of

the latter issued patent will expire at the end of the original term of the earlier issued patent. This is because the more specific "anticipates" the broader. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Allowable Subject Matter

1. Claims ~~1-9~~ 11-17, 20, 23-25, and 29-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, as well as overcoming the double patenting rejection above.
2. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the apparatus claimed by applicant. In particular, the prior art fails to disclose an extracorporeal tubing set comprising a tubing set and blood treatment components as claimed by applicant wherein the tubing set and components are secured to a mounting apparatus with the specific connections and relative elevations claimed by applicant and the components comprise *both* a VARD and an arterial filter with the claimed purge ports and vacuum lines, along with the other steps and limitations of the claims. While the prior art teaches that it is beneficial to suspend the priming solution at a height above the circuit, the prior art fails to teach the relative elevations of the remainder of the treatment components (oxygenator, pump, arterial filter, air removal device) claimed by applicant. Furthermore, applicant discloses

Art Unit: 3761

that his particular arrangement is necessary to reduce prime volume and to create an easy to use tubing and connection system. Therefore, the instant claims are patentable over the prior art.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

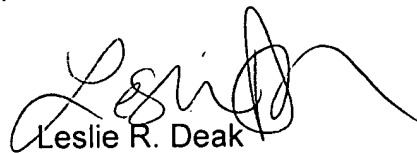
- a. US 6,299,589 Utterberg
 - i. Tubing set for dialysis devices
- b. US 6,607,698 Spears et al
 - ii. Method and tubing set for generalized extracorporeal support
- c. US 6,824,524 Favre
 - iii. Tubing for an extracorporeal circuit

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak
Patent Examiner
Art Unit 3761
27 April 2006


PATRICIA BIANCO
PRIMARY EXAMINER